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No. 95-737

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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1995

ROYCE LABORATORIES, INC.,
Petitioner,

v.

BRISTOL-MYERS SQUIBB COMPANY,
AND E.R. SQUIBB & SONS, INC.,
Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

MOTION FOR LEAVE TO FILE BRIEF AMICI CURIAE

and

BRIEF OF AMICI CURIAE NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS AND GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION, IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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MOTION FOR LEAVE TO FILE BRIEF AMICI CURIAE

This motion for leave to file a brief as amici curiae, and the annexed brief of amici curiae, is respectfully submitted pursuant to Supreme Court Rules 21 and 37, on behalf of the National Association of Pharmaceutical Manufacturers ("NAPM"), and the Generic Pharmaceutical Industry Association ("GPIA") in support of the petition for writ of certiorari filed in the above entitled matter. The annexed brief succinctly presents additional reasons, not set forth in the Petition, why the Writ should be granted in this case.

STATEMENT OF INTEREST OF AMICI CURIAE

NAPM and GPIA are national trade associations, which together for over 40 years have been important advocates for the generic drug industry in the United States. NAPM and GPIA members include manufacturers, distributors, wholesalers, and affiliated companies, who supply the American public with affordable generic pharmaceuticals, and related products. NAPM and GPIA have long played a key role in representing industry viewpoints before the courts, Congress, state legislatures, as well as various federal and state administrative bodies. It is the principal commitment and purpose of NAPM and GPIA to serve industry, consumers, and health care providers by promoting and advancing their shared interest in maintaining a competitive marketplace in which safe and effective drugs are readily available at reasonable prices. Petitioner Royce Laboratories, Inc. ("Royce") is a member of NAPM.

NAPM and GPIA have reviewed the petition for a writ of certiorari filed by Royce and concur in the substance thereof. However, upon such review, NAPM and GPIA believe that certain additional important matters should be called to the Court's attention and for that purpose seek leave to file their proposed amicus curiae brief. The proposed brief succinctly discusses the serious consequences which the decision of the United States Court of Appeals for the Federal Circuit will cause unless review is granted.

It is respectfully submitted that NAPM and GPIA, as the representatives of the generic pharmaceutical industry, should be heard with regard to the petition for a writ of certiorari, which vitally affects the interest of their members. Pursuant to Rule 37 of this Court, counsel for the respondents have been contacted to determine whether they would consent to the proposed filing of the brief. As of the date of filing, Counsel for respondents have not agreed to grant such consent. Petitioner, Royce, has consented to the filing of an amici brief by NAPM and GPIA.

It is respectfully requested that in deciding whether to grant certiorari in this matter vitally affecting the generic pharmaceutical industry, the Court should have the benefit of the additional views of that industry's trade associations. NAPM and GPIA therefore respectfully request that their motion for leave to file the annexed amicus brief be granted.

Respectfully submitted,

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QUESTION PRESENTED

NAPM and GPIA concur in the question presented in the petition for a writ of certiorari. For convenience, that question is set forth below:

> On June 8, 1995, the Uruguay Round Agreements Act ("URAA") took effect, which

inter alia grants a statutory license authorizing non-patentees to make commercial use of products subject to patents whose terms were extended by reason of the URAA. On its face, the statute applies to all such extended patents. The question presented is:

> Did the United States Court of Appeals for the Federal Circuit err when it held that as a matter of law, generic drug manufacturers cannot qualify for the URAA statutory license with regard to pharmaceutical patents whose terms have been extended by URAA?

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INTEREST OF AMICI CURIAE

The interests of amici curiae NAPM and GPIA is set forth in their motion for leave to file the instant amicus curiae brief. *See* page 2, *infra*. Accordingly it will not be repeated herein.

REASONS FOR GRANTING THE WRIT

THE DECISION OF THE FEDERAL CIRCUIT HAS FRUSTRATED THE CONGRESSIONAL EFFORT TO STRIKE A CAREFUL BALANCE BETWEEN THE INTERESTS OF THE GENERIC AND BRAND-NAME PHARMACEUTICAL INDUSTRIES IN ORDER TO ASSURE THE AMERICAN PUBLIC CAN RECEIVE AFFORDABLE GENERIC VERSIONS OF CRUCIAL DRUG THERAPIES

The Drug Price Competition And Patent Term Restoration Act

The statutory provisions at issue herein were enacted in 1984 as part of the Drug Price Competition and Patent Term Restoration Act of 1984. Pub.L. No. 98-417, 98 Stat. 1585 (the "Hatch-Waxman Act"). The prime motivating factor behind that Act was Congress' desire to facilitate the earliest possible availability of affordable generic versions of new drugs. Thus, in exchange for the one-time patent extension benefit conferred upon brand-name drug companies, Hatch-Waxman established the "Abbreviated New Drug Application" procedure by which

generic pharmaceutical companies could obtain approval to market generic versions of existing FDA-approved drugs without having to repeat the basic clinical investigations which had already been performed, and reviewed by FDA, in connection with the full New Drug Application for a particular drug.

Despite its abbreviated nature, however, the ANDA procedure still requires a generic company to conduct extensive bioequivalence and bioavailibilty studies and to submit a detailed application to the FDA. It is not unusual for the entire ANDA process to take several years from inception to final FDA approval. Increasingly, the process requires extensive investments and long-term planning in order to take advantage of marketing opportunities. Artificial delays, -- i.e. those not related to scientific/regulatory requirements -- therefore have a devastating impact on companies which have made marketing plans years in advance only to discover that their substantial capital investments have been frustrated by the inability to obtain an ANDA approval effective on the expected date.

That is the background of the instant case. The Petition for a Writ of Certiorari correctly notes that many ANDAs will be delayed. Even more pertinent is that the substantial capital investments necessary to implement those ANDAs will have been immobilized. The decision of the lower court threatens to prejudice many members of the generic drug industry and their customers during the next several years as a result of (now) misdirected capital applications toward ANDAs which cannot be approved by FDA on a timely basis.

The Uruguay Round Agreements Act

The Uruguay Round Agreements Act, Pub. L. 103-465, 108 Stat. 4809 (1994), enacted pursuant to the General Agreement on Tariffs and Trade, amended numerous provisions of federal law. Most importantly for this case, URAA amended the patent law provisions to alter how patent terms are calculated. For some pharmaceutical patents, this meant a windfall patent term extension.

However, the GATT-URAA patent term revision, 35 U.S.C. § 154, unlike the Hatch-Waxman extension, was *not* granted in order to increase incentives for basic research into new inventions, but rather was merely intended to harmonize U.S. patent law with that of our international trading partners. Thus, when Congress enacted the URAA, it recognized that the patent term revision (from 17 years from grant to 20 years from date of filing) would bestow unearned windfall patent extensions on some current patent holders, at the expense of non-patentees who had begun to prepare for the marketing of generic versions of products at the expiration of the original patent term.

To prevent such an inequitable result, Congress included one of the most important features of the URAA – a transitional statutory license provision. This "grandfather clause" was meant to protect persons who began preparing (prior to the URAA effective date of June 8, 1995) to market a generic version of a patented product on the product's original patent expiration date. It permits them to make use and sell that product *commercially* during the period between the original patent expiration date, and

the later, URAA patent expiration date (the "delta period"), subject only to the payment of "equitable remuneration" to the patent holder. 35 U.S.C. § 154(c). It is this key element of the URAA that the Federal Circuit has now read completely out of the statute with respect to generic pharmaceuticals, although they were a clear and obvious intended beneficiary of the transitional protection.

In response to the URAA's significant change in the patent law, Congress attempted to strike a careful balance between the interests of patent holders and potential competitors who have commenced actions and/or made a substantial investment toward seeking to market patented products. It is well settled that when Congress legislates, it does so with a full awareness and understanding of existing federal law. *See Bowen v. Massachusetts*, 487 U.S. 879, 896 (1988). Thus, when Congress enacted transitional "delta period" protections allowing qualifying non-patentees to market their product between the originally scheduled patent expiration date for a product, and the new URAA-established patent expiration date, Congress must have done so with the awareness that generic pharmaceutical companies would be the obvious intended beneficiaries of that protection.

The lower court's contrary ruling was thus incorrect. If not reviewed, it will have the effect of eviscerating Congressional will by creating an irrational "Catch-22" which denies generic drug companies the ability to exercise their statutory rights under the URAA transitional provisions. The Writ should be granted to review this obstruction to clear federal

law and policy in the area of pharmaceutical patents and drug regulatory approval.

CONGRESS DID NOT INTEND TO INFLICT ENORMOUS EXTRA DRUG COSTS ON THE PUBLIC DURING THE URAA TRANSITION PERIOD

In reaching its decision in this case, the Federal Circuit adopted an illogical and unnecessary interpretation of the URAA which ignores the overriding purpose of Congress in both the URAA and the Hatch-Waxman Act. That Congressional purpose was to foster and encourage the earliest possible availability of generic drugs to the American public. Utterly ignoring that Congressional imperative, the Federal Circuit went out of its way to conjure an interpretation of the URAA that attributes to Congress -- contrary to the provisions of the URAA itself -- an intention to abandon its long-held national policy goal on the basis that Congress did not expressly re-state and reaffirm that goal when enacting the URAA. Thus the panel decision noted that it could not locate any legislative history to the URAA regarding the interplay between the URAA and Hatch-Waxman Act, and purported to "limit our inquiry to the wording of the statute." *Bristol-Myers Squibb et al. v. Royce Laboratories, Inc.*, 36 USPQ2d 1641, 1646, n.4 (Fed. Cir. 1995).

In its reading of the statute, which was characterized at oral argument by one of the panel members as a "muddle," the panel reached a result which totally undermines both the Congressional intent of the Hatch-Waxman Act and the protective provisions of the URAA. Thus the lower court, based

on a lack of legislative history, discerned in the statutory muddle a Congressional intent to abandon the decade-old national priority of timely public access to affordable generic versions of life-saving pharmaceutical products, despite the presence in URAA of a provision uniquely designed to preserve that priority as to affected products. Presumably, the same lack of legislative history will not bar generic manufacturers of even the most inconsequential non-pharmaceutical products from marketing their product during the delta period. The lower court's creation of an unwritten statutory prohibition against delta period sales of ANDA-drug products cannot be allowed to stand because it jettisons Congress's, and the public's vested interest and expectation in the availability of lower cost generic drug alternatives beginning on the originally-scheduled patent expiration date.

The generic drug industry can ill afford expensive and time consuming legal battles with the brand name drug companies over the issues of implementing the URAA provisions. Moreover, because of its exclusive jurisdiction in patent matters, the decision of the Federal Circuit has laid down the law which FDA and the generic drug companies are saddled with unless this court intervenes. Indeed, contrary to the argument of Respondents Bristol-Myers Squibb Co. and E.R. Squibb & Sons, Inc., in opposition to Royce's motion to expedite consideration of its petition for certiorari, the emphatic and jurisdictionally-exclusive ruling of the Federal Circuit, in light of the requirements of Fed. R. Civ. P. 11, will mean that as a practical matter, the present case will be the only opportunity for this court to address these issues.

The outcome of this case will affect billions of dollars of either consumer cost or consumer savings, but only for one industry -- the generic pharmaceutical industry. The decision of the Federal Circuit is wrong because it because it defies common sense. It should be reversed by this court at the earliest opportunity.

CONCLUSION

For the reasons stated herein, and for the reasons stated in the Petition for Writ of Certiorari, amici curiae NAPM and GPIA respectfully urge the Court to issue the Writ and to expedite the resolution on the merits of this vitally important issue.

Respectfully submitted,

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